DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

CFN: 1123776

May 18, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Schreiber, M.D., Owner
Aerscher Diagnostics, Inc.
353 High Street
Chestertown, Maryland 21620

Dear Dr. Schreiber:

A Food and Drug Administration (FDA) inspection, conducted April 21-23, 1999 at your Chestertown and Elkton, Maryland manufacturing facilities, determined that you manufacture *in vitro* diagnostic devices (IVDs). IVDs are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Quality System Regulation (QSR) requirements (Title 21, Code of Federal Regulations (CFR), Part 820) were observed. These deviations cause your devices to be adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, storage, or holding, are not in conformance with current good manufacturing practice (CGMP) regulations. Please note that the QSR replaced the CGMP regulations for devices.

The deviations included the following:

- Failure to validate the processes used to manufacture the devices.
- Failure to ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning and use.
- Failure to ensure that all personnel have the necessary education, background, training or experience to assure that all activities required by the regulations are correctly performed.
- Failure to conduct audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the system.

- Failure to establish and maintain procedures for the control of storage areas to prevent damage, deterioration, or other adverse effects pending distribution, and to ensure that no deteriorated product is distributed. For example, the temperature and humidity in component and finished device storage areas are not monitored.

- Failure to determine storage instructions adequate to protect the stability of the product by reliable, meaningful, and specific test methods.

- Failure to maintain complete device master records. For example, device master records fail to contain specifications for incoming components, production processes, and finished devices.

- Failure to sample incoming components and finished devices based on a valid statistical rationale.

- Failure to document all production activities (e.g., to document, through inspection, testing, or verification, that incoming products and finished devices conform to specified requirements; to document the adjustment, maintenance and cleaning of production equipment; and to document the examination of incoming labeling for accuracy).

- Failure to adequately document the distribution of devices. For example, distribution records fail to include the identity of the devices shipped and control numbers used.

- Failure to maintain complete device history records. For example, device history records fail to include the primary label used for each production unit.

- Failure to maintain complete complaint files. For example, complaint files fail to include the identity of the device and control numbers used, dates of the investigation, and any reply to the complainant.

- Failure to maintain adequate procedures to control labeling activities (e.g., failure of the labeling procedure to require that labels be examined for accuracy when received).

Also, the QSR requires manufacturers to establish and maintain written procedures and documentation to assure that devices meet predetermined specifications. Since you alone perform almost all processes necessary to produce your devices, you may be able to maintain control of the process without extensive written procedures. However, without certain written reminders, you are risking the possibility of distributing non-conforming product and failing to make necessary reports to FDA, to calibrate or adjust production equipment adequately, to document changes in design, etc. Therefore, it is in your best interest to conform to regulations regarding written procedures and documentation.

At the conclusion of the inspection, you were given a written list of inspectional observations (FDA-483) which were discussed with you.

We acknowledge that you responded to the FDA-483 in a letter dated April 25, 1999. We have reviewed your response and consider it to be inadequate for the following reasons:

- You have not listed specific actions you will be taking to correct the observations on the FDA-483.

- You have not indicated when you anticipate that you will complete these corrections.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facilities. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when awarding contracts. Additionally, no pre-market submissions for devices to which the QSR deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District